

QUESTION AND ANSWER SESSION

RAVI BASAVAPPA: IT IS NOW TIME TO ANSWER QUESTIONS ABOUT THE TRANSFORMATIVE RESEARCH AWARD. WE WILL BEGIN WITH QUESTIONS THAT HAVE BEEN SUBMITTED IN ADVANCE, THEN MOVE ONTO TAKING YOUR QUESTIONS LIVE ON PHONE OR VIA E-MAIL. THE PHONE LINE WILL BE OPENED NOW SO YOU CAN START CALLING IN. THE MEMBERS OF THE HIGH RISK, HIGH REWARD PROJECT TEAM ARE HERE WITH ME AND WILL BE HELPING TO ANSWER YOUR QUESTIONS.

QUESTIONS:

1. WHY ARE THERE SO FEW CLINICAL AND BEHAVIORAL PROJECTS FUNDED?

THE ISSUE WITH CLINICAL AND BEHAVIORAL RESEARCH PROJECTS IS ACTUALLY A COMPLICATED ONE IN THAT IN THE FIRST YEARS OF THIS PROGRAM, WE ACTUALLY DIDN'T GET A LOT OF APPLICATIONS IN THOSE AREAS, AND EVEN THOUGH WE GOT A FEW APPLICATIONS IN THOSE AREAS, GENERALLY THEY DIDN'T TEND TO REVIEW WELL. THE WAY WE RESPONDED TO THAT WAS, IN PART, TO TRY TO ENCOURAGE PEOPLE TO CONSIDER THIS PROGRAM IF THEY'RE LOOKING AT A CLINICAL STUDY OR A BEHAVIORAL STUDY THAT THEY THINK HAS POTENTIAL FOR VERY HIGH IMPACT BECAUSE, OF COURSE, THE NIH CONSISTS OF INSTITUTES THAT ARE INTERESTED IN ALL REALMS OF SCIENCE, NOT JUST BASIC SCIENCE AND WIDGET DEVELOPMENT. WHAT WE DID FIRST WAS TRY TO ENCOURAGE PEOPLE TO SUBMIT, WHICH WAS A MAJOR ISSUE FOR THE FIRST COUPLE OF ROUNDS. THEN THE SECOND THING WAS JOHN BOWERS, WHO YOU JUST HEARD FROM, RESPONDED TO THIS CONCERN BY MAKING SURE THAT WE HAD ON THE EDITORIAL BOARD INDIVIDUALS WHO ARE SENSITIVE AND RECEPTIVE TO THOSE TYPES OF STUDIES SO THAT WE CAN BE SURE THAT THEY GET A FAIR HEARING FROM THE REVIEW BOARD. SO I THINK WE ALL RECOGNIZE THAT WE WOULD LIKE TO SEE MORE CLINICAL RESEARCH AND MORE BEHAVIORAL STUDIES COMING IN THROUGH THIS PROGRAM AND WE WANT TO ENCOURAGE PEOPLE AND WE WANT PEOPLE TO NOT BE DISCOURAGED BY LOOKING AT WHAT'S BEEN AWARDED HISTORICALLY BECAUSE THE EARLY ROUND, OF COURSE, DID HAVE A LOT OF BASIC SCIENCE AWARDS. SO, WE'RE CONTINUING TO WORK TOWARDS ENCOURAGING THOSE KINDS OF STUDIES TO COME IN, IN THE FUTURE.

2. WHAT ARE THE EXPECTATIONS REGARDING PRELIMINARY DATA?

I WANT TO START BY REFERRING TO SOMETHING THAT RAVI SAID EARLIER WHEN HE WAS DESCRIBING WHAT'S DIFFERENT ABOUT THESE TRANSFORMATIVE PROJECTS, WHICH IS THAT THEY TEND TO BE RISKIER THAN CONVENTIONAL PROJECTS SOLELY BECAUSE SOME COMPONENT OF A GOOD TRANSFORMATIVE PROJECT INVOLVED SAILING INTO UNCHARTED TERRITORY. FOR THAT REASON, ANYBODY WHO IS CONSIDERING ASPECTS OF THESE PROJECTS ARE TOLD TO ONLY CONSIDER RISK IN ONE CONTEXT WHICH IS, "IS THERE ABSOLUTELY NO POSSIBILITY WHATSOEVER THAT THE PROJECT WILL SUCCEED?" AND IF IN A REVIEWER'S OPINION THAT'S THE CASE, THEN THAT PERSON CAN LEGITIMATELY SCORE THE APPLICATION LOWER OR NOT SCORE IT AT ALL. AND IF THERE'S ANY PROBABILITY, HOWEVER SMALL, THAT THE PROJECT WILL SUCCEED, YOU TAKE RISK OUT OF THE EQUATION AND DON'T TALK ABOUT IT

ANYMORE. THAT'S OUR METHOD OF ACCOMMODATING THE RISKINESS IN MOST OF THESE PROJECTS -- THE GOOD ONES AT ANY RATE. HOWEVER, KEEP IN MIND THAT SOMETIMES THE QUESTION OF "IS THERE ANY PROBABILITY WHATSOEVER THAT THIS PROJECT WILL SUCCEED?" DOES ARISE IN REVIEW OR WHEN FUNDING DECISIONS ARE MADE, AND UNDER SOME CIRCUMSTANCES A LITTLE BIT OF PRELIMINARY DATA MIGHT BE A GOOD IDEA TO REASSURE PEOPLE THAT THERE'S AT LEAST A LITTLE BIT OF PROBABILITY THAT THAT COULD WORK, AND IN WHICH CASE, IT'S APPROPRIATE TO INCLUDE PRELIMINARY DATA. BUT I DO WANT TO GO BACK TO ONE OTHER THING THAT RAVI SAID WHICH IS THERE ARE BASICALLY WAYS OF CONVINCING PEOPLE THAT THE PROJECT HAS SOME LIKELIHOOD OF WORKING AND PRELIMINARY DATA ARE ONLY ONE OF THESE THREE WAYS. YOU CAN USE ANY COMBINATION OF THESE THINGS DEPENDING ON YOUR CIRCUMSTANCES. ONE INDICATOR IS IF YOU HAVE THE TRACK RECORD FOR SOLVING TOUGH PROBLEMS AND MAKING INNOVATIVE DISCOVERIES. I DO WANT TO ITERATE THAT EVEN IF YOU'RE A YOUNG INVESTIGATOR YOU MAY HAVE A TRACK RECORD BECAUSE YOU CAN DEMONSTRATE YOUR INNOVATION AND YOUR ABILITY TO SOLVE TOUGH PROBLEMS WHEN YOU'RE A POST DOC OR GRAD STUDENT. YOU CAN USE THIS FACTOR IF YOU'VE EVER, EVER HAD THIS KIND OF EXPERIENCE AND YOU SHOULD EMPHASIZE THIS SORT OF THING IN YOUR BIOSKETCH. THE SECOND WAY TO CONVINCE REVIEWERS IS BY THE LOGIC OF YOUR EXPERIMENTAL PLAN, THAT YEAH, THERE ARE SOME ODDS THIS THING WILL WORK. YOU MUST BE CONVINCING THAT YOU THOUGHT THIS THROUGH REALLY CAREFULLY, AND IF ANYBODY CAN MAKE IT WORK, YOU CAN. THE THIRD IS MAYBE YOU CAN INCLUDE PRELIMINARY DATA. PRELIMINARY DATA ARE NOT REQUIRED BUT ARE SOMETIMES VALUABLE.

THE SECOND QUESTION THAT COMES UP WITH REGARD TO PRELIMINARY DATA IS "WHERE DO YOU PUT IT?" IF YOU LOOK AT THE FORMAT OF A TRANSFORMATIVE APPLICATION, AS RAVI MENTIONED, THE RESEARCH STRATEGY SECTION INVOLVES ANSWERING QUESTIONS. YOU KNOW WHAT YOU'RE GOING TO DO, WHAT THE EVIDENCE IS THAT YOU CAN DO IT, THAT SORT OF THING, BUT THERE'S NO SECTION THAT SAYS "TELL US ABOUT YOUR PRELIMINARY DATA." IF YOU HAVE SOME, AND DECIDE TO INCLUDE IT BECAUSE YOU THINK IT WOULD BE VALUABLE, WE WANT YOU TO INCLUDE IT IN WHATEVER ANSWER TO THE QUESTIONS THAT SEEMS LOGICAL. IN OTHER WORDS, DON'T CREATE A SECTION THAT SAYS "PRELIMINARY DATA." WE'RE NOT LOOKING FOR THAT. PUT IT IN THE SECTION DESCRIBING HOW IN GENERAL YOU'RE GOING TO DO WHAT YOU'RE WANTING TO DO. LIKE MAYBE THE INNOVATION SECTION. USE YOUR JUDGMENT. JUST FIT IT IN SOMEHOW IN RESPONSE TO THE ANSWERS TO ONE OR MORE QUESTIONS. SO IN SUMMARY WHAT I WANT TO SAY IS THAT YOU DON'T NEED PRELIMINARY DATA. THERE ARE APPLICATIONS THAT HAVE BEEN FUNDED IN THE PAST AND I'M SURE IN THE FUTURE THAT HAVE NO PRELIMINARY DATA OR VERY, VERY LITTLE, BUT IF YOU HAVE SOME, YOU'RE WELCOME TO INCLUDE IT. JUST INCLUDE IT IN RESPONSE TO ONE OR MORE OF THE QUESTIONS THAT ARE BEING ASKED FOR THE RESEARCH STRATEGY SECTION.

3. WHAT ARE THE MOST COMMON CRITICISMS OF APPLICATIONS?

AS YOU MIGHT EXPECT, THE MOST COMMON CRITICISMS ARE THAT THE APPLICATIONS DON'T HIT ALL HIGH POINTS OF EMPHASIS: SIGNIFICANCE, IMPACT, AND INNOVATION. SO JOHN HAS

DONE A REALLY EXCELLENT JOB OF INSTRUCTING THE REVIEWERS TO FOCUS ON THESE PARTICULAR ASPECTS OF THE APPLICATION. SO IF THE APPLICATIONS ARE WRITTEN SUCH THAT IT IS NOT EASILY APPARENT THAT WHAT YOU PROPOSE HAS SUBSTANTIAL SIGNIFICANCE, THAT IT HAS EXCEPTIONAL INNOVATION, AND THAT THE IMPACT IS BROAD, THEN IT'S MOST LIKELY NOT GOING TO DO WELL IN THE REVIEW. SO I MIGHT SUGGEST THAT BEFORE YOU ACTUALLY WRITE YOUR PROPOSAL, YOU ACTUALLY ASK SOME OF YOUR COLLEAGUES WHAT THEY THINK. IN A MINUTE OR TWO DESCRIBE WHAT YOU ARE THINKING ABOUT PROPOSING AND SEE WHAT THEY SAY. IF THEY SAY, "SO WHAT" AFTER LISTENING TO YOU, THEN IT'S NOT A GOOD SIGN. BUT IF THEY SEEM TO GET EXCITED, ESPECIALLY IF THEY ARE COLLEAGUES WHO ARE OUTSIDE YOUR FIELD, THEN I WOULD PROPOSE ELABORATING ON THE IDEA AND ACTUALLY PUTTING IN A PROPOSAL.

4. HOW CAN APPLICATIONS WITH SUCH DIVERSE TOPICS BE REASONABLY REVIEWED BY A SINGLE PANEL?

I KIND OF WENT OVER THIS WITH THE PRESENTATION OF THE REVIEW FORMAT, BUT BASICALLY THE EDITORS ARE GENERALISTS, AND THEIR INPUT IS FOLLOWED BY INPUT FROM SUBJECT MATTER EXPERTS, AND THEN THE APPLICATION GOES BACK TO THE GENERALISTS. SO WE GET A BROAD PERSPECTIVE, THEN WE DRILL DOWN AND GET THE INPUT OF SUBJECT MATTER EXPERTS, AND THEN IT GOES BACK TO GENERALISTS. THAT'S THE WAY WE DO IT.

5. WOULD A POPULATION-BASE/COHORT STUDY BE FUNDABLE?

SOME OF THE THINGS WE DON'T WANT TO USE THE TRA MECHANISM FOR IS TO COVER LARGE EXPENSES FOR PROJECTS WHERE YOU'RE LOOKING TO CONTINUE AN ONGOING STUDY. IF WHAT YOU'RE PROPOSING TO DO HAS A TRANSFORMATIVE ASPECT, AND THAT WOULD BE WHERE YOU COULD REALLY MAKE SIGNIFICANT HEADWAY IN THE FIVE-YEAR PERIOD, I THINK THAT THIS WOULD BE FINE. IN TERMS OF MAINTENANCE OF THE SPECIMEN BANK, AGAIN, IF THIS IS SOMETHING THAT YOU NEED FOR PART OF A STUDY AND DURING THE PERIOD OF THE STUDY, TO INCLUDE AS AN EXPENSE IN THE APPLICATION WOULD BE FINE. IF THE INTENT IS TO TRY TO USE THE MECHANISM FOR SUCH PURPOSE, THEN I THINK THERE ARE OTHER MECHANISMS THAT WOULD BE BETTER SUITED FOR THIS.

6. IF APPLICATIONS DON'T HAVE MAJOR FLAWS THEN WHY DO THEY GET SCORES OF TWO OR THREE?

THIS IS REALLY MORE OF A GENERAL REVIEW QUESTION THAN ANYTHING SPECIFIC TO THE TRA PROGRAM. BASICALLY, A SCORE OF ONE IS SOMETHING THAT STUDY SECTIONS ARE TOLD IS A RARE EVENT, BASICALLY A PERFECT APPLICATION THAT IS FLAWLESS. MOST REVIEWERS MIGHT EXPECT TO SEE ONE APPLICATION EVERY COUPLE CYCLES OR ONCE A YEAR THAT WOULD RECEIVE A SCORE OF ONE. WE TRY VERY HARD TO MAKE "ONES" A RARE EVENT. ANYTHING THAT RECEIVES A SCORE -- AND I'M TALKING NOW ABOUT INDIVIDUAL CRITERIA SCORES -- OF A THREE OR HIGHER SHOULD ACTUALLY HAVE A WEAKNESS HIGHLIGHTED FOR IT IN THE SUMMARY STATEMENT. A SCORE OF TWO IS KIND OF MIDDLE GROUND -- IT'S NOT PERFECT,

BUT IT'S PRETTY DARN GOOD. SO THAT'S JUST GENERAL NIH PEER REVIEW. THERE IS NOTHING REALLY SPECIFIC TO THE TRA AWARDS.

7. HOW MANY PROPOSALS DO YOU ANTICIPATE BEING SUBMITTED AND WHAT IS THE FUNDING PROBABILITY?

OVER THE PAST FEW YEARS, SINCE 2009, WE'VE RECEIVED ABOVE 250 APPLICATIONS EACH ROUND. WE ANTICIPATE WE'LL RECEIVE SEVERAL HUNDRED DUE TO OUR OUTREACH EFFORTS THIS ROUND. AS YOU MIGHT IMAGINE, THE FUNDING RATE FOR TRANSFORMATIVE RESEARCH AWARD PROPOSALS IS MORE COMPETITIVE THAN A CONVENTIONAL RO1 APPLICATION, AND IS IN THE SINGLE DIGITS.

8. FOR A NEW PI, IS AN APPLICATION WITH A DIRECT COST REQUEST OF NEAR \$550,000; IS THAT SUCH AN APPLICATION FUNDABLE?

WHAT YOU NEED TO KEEP IN MIND WITH THE LEVEL OF SUPPORT YOU REQUEST IS WHAT AMOUNT OF BUDGET IS REQUIRED TO GET DONE WHAT YOU'RE PROPOSING TO DO. THE MAIN DECISION THAT'S GOING INTO WHETHER SOMETHING IS GOING TO MOVE FORWARD THROUGH THE EDITORIAL BOARD AND INTO AWARD PHASE HAS TO DO WITH THE STUDY ITSELF. WHAT YOU DON'T WANT TO DO IS ANTICIPATE GETTING A RESPONSE THAT YOU'RE BUDGET IS TOO HIGH AND THEN LOW-BALL THE BUDGET. WHAT YOU NEED TO DO IS THINK ABOUT THE STUDY, THINK ABOUT HOW EXPENSIVE THE STUDY IS GOING TO BE, AND BE REALISTIC ABOUT THE BUDGET YOU'RE REQUESTING. WHETHER IT'S A NEW PI OR AN ESTABLISHED PI, IT'S REALLY THE BUDGET THAT'S REQUIRED TO GET THE WORK DONE, AND THAT'S THE BOTTOM-LINE. I DON'T SEE THAT THERE'S NECESSARILY A DIFFERENT SCALE FOR NEW PI AS VERSUS AN ESTABLISHED PI. IF THE REVIEW PANEL BUYS INTO THE PROJECT, THEY THINK IT'S WORTH DOING, AND THEY THINK THAT YOU'RE THE RIGHT PERSON TO DO IT, THEN WE'RE LOOKING AT IT AS IS THIS AN APPROPRIATE INVESTMENT FOR THE PROGRAM. WE WANT TO GET THE FUNDS BEHIND WHAT IS REQUIRED TO MAKE A GOOD FAITH EFFORT AT THE PROJECT. SO I WOULD NOT, AS I SAID, TRY TO ANTICIPATE SOMETHING AS BEING A SMALLER BUDGET THAN WHAT IS ACTUALLY REQUIRED, BECAUSE WHAT HAPPENS, ESPECIALLY IF YOU'RE A NEW INVESTIGATOR, IS THAT IT RAISES A QUESTION IN THE MIND OF THE REVIEW PANEL THAT MAYBE YOU'RE NOT REALISTIC AND YOU DON'T KNOW HOW TO ANTICIPATE HOW EXPENSIVE THINGS ARE.

9. THERE IS NO MENTION OF INSTITUTIONAL SUPPORT OR INTERNAL COMMITTEE. PLEASE COMMENT IF SUCH THINGS ARE REQUIRED OR ENCOURAGED.

YOUR APPLICATION IS SUBMITTED WITH THE APPROVAL OF YOUR INSTITUTION AND INSTITUTIONAL SUPPORT IS EXPECTED AS PHYSICAL RESOURCES AND EQUIPMENT. IN RESPONSE TO THE SECOND PART OF QUESTION, **"ARE INTERNAL ADVISORY AND REVIEW COMMITTEES ALLOWED?"** THE ANSWER IS YES, THEY ARE. THEY COULD BE INCLUDED IN PERSONNEL JUSTIFICATIONS, IN THE MULTI-PI LEADERSHIP PLAN IF APPLICABLE, OR WITH TIMELINE INFORMATION THAT'S REQUIRED IN THE APPLICATION.

10. WILL NEW PIs BE JUDGED ONLY ON APPROPRIATE EXPERIENCE AND TRAINING?

WHEN PUTTING TOGETHER A TEAM FOR AN APPLICATION, THE TEAM SHOULD HAVE THE NECESSARY AND APPROPRIATE KNOWLEDGE, SKILLS, AND RESOURCES TO BE ABLE TO TACKLE THE PROBLEM, AND EACH MEMBER OF THE TEAM SHOULD BE CONTRIBUTING EFFORT TO INCREASE THE LIKELIHOOD OF SUCCESS FOR THE PROJECT. AS RAVI MENTIONED EARLIER, NEARLY A THIRD OF THE TRANSFORMATIVE RESEARCH AWARDS HAVE BEEN TO MULTI-PI APPLICATIONS BECAUSE OF THE MULTIDISCIPLINARY NATURE AND THE VERY BROAD VISION OF MOST OF THE APPLICATION AND APPROPRIATE FOR IT TO HAVE A GOOD TEAM OF INVESTIGATORS INVOLVED.

11. IS IT BETTER IF SENIOR COLLABORATORS ARE CO-PIs OR CO-INVESTIGATORS?

TO REITERATE THE POINT MADE IN THE PREVIOUS ANSWER, BECAUSE THIS IS NOT A STANDARD RO1 AWARD, THERE'S NO ADVANTAGE GIVEN TO EARLY INVESTIGATORS OR NEW INVESTIGATORS, BUT EACH MEMBER OF THE TEAM SHOULD BE COMING TOGETHER AND EACH MEMBER OF THE TEAM SHOULD INCREASE THE LIKELIHOOD OF SUCCESS FOR THE OVERALL PROJECT. APPLICATIONS GENERALLY ARE BRINGING TOGETHER INVESTIGATORS WITH DIFFERENT SKILLS AND RESOURCES, SO WHATEVER'S MOST APPROPRIATE FOR THE RESEARCH PLAN BEING PROPOSED.

12. ARE LETTERS OF SUPPORT ENCOURAGED OR NECESSARY COMPONENT OF TRA APPLICATIONS?

FOR LETTERS OF SUPPORT, IT ALL DEPENDS ON WHETHER YOU THINK YOU HAVE THE EXPERTISE THAT'S NECESSARY FOR WHAT'S PROPOSED COVERED EITHER BY YOU OR BY OTHER MULTI PI ON THE PROPOSAL, THEN LETTERS OF SUPPORT ARE NOT NECESSARY. BUT IF THEY ARE CRITICAL ELEMENTS OR EXPERTISE OR EVEN REAGENTS, FOR EXAMPLE, THAT WOULD BE NECESSARY FOR THE PROPOSAL, THEN IT CERTAINLY WOULD MAKE SENSE TO INCLUDE LETTERS OF SUPPORT.

13. HOW MANY APPLICATION CYCLES ARE THERE EACH YEAR?

ONE. THERE'S ONLY ONE APPLICATION CYCLE PER YEAR. THIS YEAR IT IS JANUARY 12TH.

14. CAN PEOPLE FROM INDUSTRY APPLY? HAS AN AWARD BEEN MADE TO A SMALL BUSINESS?

THEY CERTAINLY CAN APPLY AND WE HAVE RECEIVED QUITE A FEW APPLICATIONS FROM INDUSTRY, BUT I DON'T THINK WE'VE ACTUALLY MADE AN AWARD TO A BUSINESS.

15. IS THERE A BUDGET CAP?

NO, THERE'S ESSENTIALLY NO DOLLAR AMOUNT THAT APPLICANTS ARE ADVISED NOT TO EXCEED. THE BUDGETS CAN BE UP TO \$25 MILLION PER YEAR. OF THE 80 OR SO AWARDS MADE TO DATE, AT LEAST FIVE HAVE BUDGETS GREATER THAN OR CLOSER TO \$1.5 MILLION IN TOTAL DIRECT COSTS PER YEAR. THE IMPORTANT THING TO REMEMBER IS THAT THE BUDGET SHOULD BE COMMENSURATE WITH THE NEEDS OF THE PROJECT AND THE SCOPE OF THE PROJECT. I THINK UP TO ONE-THIRD OF THE BUDGET IS RESERVED FOR PROJECTS THAT EXCEED 1 MILLION DOLLARS.

16. WOULD USING PREVIOUS CLINICAL SAMPLES TO DO SOMETHING NOVEL DETRACT FROM THAT APPLICATION?

ONCE AGAIN, EMPHASIZING THE TRANSFORMATIVE NATURE OF WHAT IS IT YOU'RE TRYING TO DO, I THINK THAT LEVERAGING EXISTING DATA TO CONDUCT SECONDARY ANALYSIS WHERE EITHER THE ANALYSIS, ITSELF, IS BEING CONDUCTED IN A NEW WAY THAT MIGHT BLAZE A TRAIL FOR ANALYSES OF OTHER DATA SETS, COULD CERTAINLY FIT THE TRANSFORMATIVE NATURE THAT WE WOULD BE LOOKING FOR. STANDARD SECONDARY DATA ANALYSIS MAY BE BETTER SUITED FOR A MORE TRADITIONAL FUNDING ROUTE, BUT AS LONG AS WHAT YOU'RE LOOKING FOR IS GOING TO BE TRANSFORMATIVE, THEN I WOULD ENCOURAGE YOU TO PUT IN THE APPLICATION. MAKE SURE IT'S VERY CLEAR AND APPARENT TO THE REVIEWERS WHO ARE LOOKING AT THE APPLICATION WHAT IS TRANSFORMATIVE ABOUT WHAT YOU'RE PROPOSING TO DO SO THAT THEY DON'T HAVE TO DO ANY GUESS WORK BUT, BUT YES, ABSOLUTELY.

17. WILL THE REVIEW CHANGE TO GIVE BASIC BEHAVIORAL AND CLINICAL PROJECTS EQUAL REPRESENTATION?

CONSIDERING EITHER THE EDITORIAL PANEL, THE PANEL ACTUALLY HAS AN OVERREPRESENTATION OF PEOPLE WORKING IN THESE AREAS. CERTAINLY LAST YEAR, HALF THE PEOPLE ON THE BOARD WERE FROM AREAS OF BASIC AND BEHAVIORAL RESEARCH, AND THERE ARE ALWAYS SOME REVIEWERS WHO DO THAT TYPE OF WORK. SO WE'RE NOT MAKING ANY HUGE CHANGES TO THE REVIEW PROCESS THIS YEAR. IT WOULD BE PRETTY MUCH AS IT WAS LAST YEAR.

18. WOULD A NOVEL APPROACH TO RESEARCH TRANSLATION WITH MORE RAPID APPLICATION OF THE IOM RAPID LEARNING HEALTH CARE SYSTEM PRINCIPLE BE REGARDED AS FUNDABLE?

I WOULD SAY, ABSOLUTELY, PARTICULARLY IF THE STRATEGY THAT YOU'RE PROPOSING WOULD BE BROADLY APPLICABLE. AS YOU ARE PROBABLY AWARE, DISSEMINATION/IMPLICATION OF EVIDENCE-BASED PRACTICES IS A HUGE CHALLENGE RIGHT NOW. SO ANYTHING YOU CAN DO TO DEVELOP A STRATEGY OR AN APPROACH THAT COULD BE BROADLY APPLIED, OR MAYBE REQUIRE SOME MINOR TWEAKING FOR DIFFERENT FIELDS, WOULD CERTAINLY BE ATTRACTIVE AND BE POTENTIALLY TRANSFORMATIVE.

19. HOW DOES HAVING A PAST PIONEER AWARD HELP?

IT REALLY DOESN'T MAKE ANY DIFFERENCE AT ALL. IT CERTAINLY DOESN'T HURT BUT IT DOESN'T NECESSARILY HELP EITHER. FROM THE POINT OF VIEW OF, PERHAPS, YOUR PIONEER AWARD SHOWS YOU'RE PARTICULARLY INNOVATIVE AND HAVE A TRACK RECORD GAME-CHANGING RESEARCH, THEN IT DOES NOT HURT. IT WOULD JUST BE CONSIDERED ALONG WITH ALL THE OTHER FACTORS.

20. DOES NCCAM HAVE THE TRANSFORMATIVE RESEARCH AWARD MECHANISMS AND WILL A PI BE ABLE TO APPLY UNDER IT?

THE TRANSFORMATIVE AWARD PROGRAM IS ADMINISTERED BY THE COMMON FUND WHICH IS INDEPENDENT OF THE INDIVIDUAL NIH INSTITUTE. SO AN APPLICATION THAT WOULD BE RELEVANT TO NCCAM WOULD BE ELIGIBLE TO BE SUBMITTED FOR THIS FUNDING OPPORTUNITY ANNOUNCEMENT. IF IT WERE FUNDED, THEN IT IS HIGHLY LIKELY THAT, THE PROGRAM DIRECTOR AT NCCAM WOULD ADMINISTER THE AWARD.

21. OFTEN THE EXPERTS IN THE FIELD HAVE ESTABLISHED STATUS QUO. THE TRANSFORMATIVE RESEARCH INITIATIVE IS MEANT IN A WAY TO CHALLENGE STATUS QUO. WHAT HAPPENS WHEN THE EDITORS THINK THAT REVIEWERS ARE BEING TOO CRITICAL ABOUT THE WAY THEIR PROJECT COULD WORK?

THE EDITORS ACTUALLY PLAY A CRUCIAL INTERPRETIVE ROLE IN THIS PROCESS AND THAT'S FOR A COUPLE OF REASONS. ONE IS THEY ARE THE MOST IN TOUCH WITH THE PROGRAM AND THE GOALS OF THE PROGRAM. THE MAIL REVIEWERS AT TIMES CAN REVIEW THINGS A BIT MORE LIKE A CONVENTIONAL RO1, AND THE EDITORS DO IN FACT TAKE THAT INTO ACCOUNT, AND QUITE FREQUENTLY, CHOOSE TO DISCOUNT THE COMMENT BECAUSE OF THIS REASON OR THAT REASON. THE EDITORS REALLY ARE A FILTER AND TAKE THE REVIEWERS PERSPECTIVE INTO ACCOUNT.

22. REGARDING BUDGETING, WHAT ABOUT ACQUISITION OF EQUIPMENT?

YES, IT IS ALLOWED. AS WITH THE REGULAR RO1, THE COSTS CAN BE INCLUDED IF THEY'RE APPROPRIATE AND IF THE RESOURCES AT THE INSTITUTES AREN'T ALREADY AVAILABLE, BUT THERE HAVE BEEN LIMITS PLACED ON SUCH REQUESTS. THE TEAM SHOULD BE ABLE TO TACKLE WHATEVER PROJECT THEY'RE PROPOSING, BUT OBVIOUSLY THERE'S ROOM TO INCLUDE THESE COSTS AS WELL.

23. CAN COLLABORATORS FROM ANOTHER COUNTRY BE SUPPORTED TO RECEIVE FUNDS THROUGH THE PROGRAM?

IN THIS CASE, THE RULES ARE THE SAME AS FOR A CONVENTION RO1 AWARD. IN OTHER WORDS, YES, A COLLABORATOR CAN BE FROM ANOTHER COUNTRY. I DO WANT TO CAUTION YOU THAT IF THE COLLABORATOR FROM ANOTHER COUNTRY-- WHO IS WORKING IN ANOTHER COUNTRY -- IS THE PI, THAT JUST LIKE CONVENTIONAL RO1s, THE REVIEWERS ACTUALLY LOOK AT ONE MORE CRITERION WHICH IS, "IS THERE SOMETHING SPECIAL ABOUT WHERE THE PI IS?" IT DOESN'T HAVE TO BE UNIQUE, BUT "IS IT EXCEPTIONALLY GOOD?" IN THIS RESPECT, APPLICATIONS FROM FOREIGN PIs, WHETHER THEY'RE CO-PIs OR INDIVIDUAL PIs, ARE TREATED THE SAME WAY AS CONVENTIONAL RO1 APPLICATIONS. FOR THE SECOND QUESTION, "IS IT BEST TO PRESENT A PROJECT WHERE THERE IS STRONG EMPIRICAL EVIDENCE SUCH AS EFFECTIVENESS?", IF THERE ARE DATA THAT CAN'T BE EXPLAINED BUT PROVIDE GOOD PREMISE FOR A TRANSFORMATIVE RESEARCH AWARD APPLICATION, THEN CERTAINLY YOU COULD PROPOSE A HYPOTHESIS TO EXPLAIN THE DATA.

24. CAN THE TRA PROPOSAL INCLUDE CLINICAL TRIALS AND USE ANIMAL MODELS?

YES.

25. WHAT WOULD BE CONSIDERED NEW CONCEPTS IN A CLINICAL TRIAL? ANY CONCEPTS FOR EXAMPLE?

ONE EXAMPLE IS, WHAT WE'VE SEEN WITH SHEILA MURPHYS PROJECT THAT THE VIDEO DESCRIBED. WE'RE TRYING TO ENCOURAGE AND NOT TO SWAY PEOPLE FROM ENGAGING IN CLINICAL TRIALS. THERE MAY BE RISK INVOLVED AND NIH HAS POLICIES THAT ADDRESS THAT RISK.

26. CAN A MORE FOCUSED VERSION OF THE TR01 APPLICATION FOR REGULAR R01 SUPPORT BE SUBMITTED FOR THE FOLLOWING DEADLINE?

YOU CAN'T HAVE THEM IN REVIEW AT THE SAME TIME. THE WAY NIH DEFINES "DIFFERENT TIMES" IS IF A SUMMARY STATEMENT HAS BEEN RELEASED. IF THE TRA SUMMARY STATEMENT HAS BEEN RELEASED, THEN YOU'RE FREE TO GO AHEAD AND SUBMIT THE APPLICATION SOMEWHERE ELSE.

27. CAN A HIGHLY-INNOVATIVE PROJECT WITH LARGE REWARD BUT LOW RISK BE FUNDABLE? HOW DOES THAT NEED TO BE PRESENTED?

NO, THAT WOULD BE MORE APPROPRIATE FOR A TRADITIONAL R01 APPLICATION.

28. I THOUGHT I READ IN THE RFA THAT WE WERE NOT ALLOWED TO HAVE ATTACHMENTS. IF THIS IS TRUE, WHERE DO WE ATTACH THE LETTERS OF SUPPORT?

ACCORDING TO JOHN BOWERS, THE TRA PROGRAM REVIEW LEAD, IT WOULD COME AFTER THE RESEARCH PLAN.

RAVI BASAVAPPA: IF THERE ARE NO FURTHER QUESTIONS, THEN WE WILL CLOSE THIS WEBINAR. THANK YOU VERY MUCH. I HOPE YOU FOUND IT INFORMATIVE AND USEFUL. BECAUSE SO MANY PEOPLE WERE TRYING TO LOG IN AT ONCE, THE NIH SERVER WAS NOT ABLE TO HANDLE THE VOLUME. THE WEBINAR TRANSCRIPT WILL BE ARCHIVED AND AVAILBALE FOR LATER VIEWING. PLEASE VISIT THE COMMON FUND WEB SITE FOR THE ARCHIVE. THANK YOU.